

REMARKS

Claims 1-14 are pending in this application. Claims 5-14 were rejected under 35 U.S.C. § 102. Claims 1-4 were rejected under 35 U.S.C. § 103.

Amendment To The Specification

In the Office Action mailed on April 5, 2005, the Examiner notes that “none of the certified copies of the priority documents have been received.” Upon inspection of the specification, Applicant noted that an incorrect Korean application serial number was provided under the heading “Cross-Reference To Related Applications.” Therefore, in order to correct this inadvertent error, Applicant hereby amends the specification to reflect the correct Korean application serial number to which priority is claimed by the present application for patent.

Additionally, submitted herewith is a corrected Application Data Sheet that reflects the correct Korean application serial number to which priority is claimed under 35 U.S.C. § 119(a).

Applicant has ordered a certified copy of this Korean application and will submit the certified copy to the Examiner as soon as possible.

The Rejection Under 35 U.S.C. § 102

Claims 5-14 were rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by *Justis et al.* (U.S. Patent No. 6,530,929). Applicants respectfully traverse this rejection.

Regarding claim 5, the Examiner alleges that *Justis et al.* disclose a marking and guidance system for use during spinal surgery, comprising a means (280) for marking a location of an entry point on a vertebral bone for subsequent implantation of a securing member (61) of a spinal fixation device. Claim 5 recites a “means for marking a location of an entry point on a vertebral bone for subsequent implantation of a securing member of a spinal fixation device.” Under 35 U.S.C. 112, sixth paragraph, this claim “shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.” As described in the

specification of the present application for patent, the corresponding structures are specifically designed to facilitate insertion of fiducial pins in order to overcome disadvantages of prior systems that use guidewires, such as the system disclosed by Justis *et al.* Thus, while both inventions involve the implantation of a securing member of a spinal fixation device, Justis *et al.* teaches the use of a guidewire (280) for marking the location (Justis, column 12, lines 44-46). On the other hand, the current invention was made as an improvement of the guidewire system. (p. 7, line 12-26; p. 8, lines 1-15). More specifically, this invention uses fiducial pins (110 and 112) to mark the location of an entry point, which are made of a durable and rigid biocompatible material for easy insertion into the pedicle bone (p. 26 lines 9-26; p.27 lines 1-2). Applicants respectfully submit that Justis *et al.* neither disclose nor suggest a system that uses fiducial pins (a.k.a., marking pins).

Accordingly, Applicants respectfully submit that claim 5 is neither anticipated nor rendered obvious by Justis *et al.* and that claim 5 is now in condition for allowance. Because claims 6-7 are dependent upon claim 5, Applicants respectfully submit that these claims are also in condition for allowance.

Claims 8-11 were rejected because the Examiner believes that the method steps as set forth would have been inherently carried out in the operation of the device described in Justis *et al.* Claim 8 recites “inserting a marking pin at or near a desired entry point” As discussed above, Applicants respectfully submit that Justis *et al.* neither disclose nor suggest the use of a marking pin. Thus, it is impossible that the method steps of claim 8 would be inherently carried out by the device described in Justis *et al.* Accordingly, Applicants respectfully submit that claim 8 is patentably distinguishable over Justis *et al.* and in condition for allowance. Because claims 9-11 are dependent upon claim 8, Applicants submit these claims are also in condition for allowance.

Regarding claim 12, the Examiner alleges that it is anticipated by Justis *et al.* As discussed above, Justis *et al.* does not disclose a means for inserting a marking pin at or near a desired entry point on a vertebral bone of a patient’s spinal column, because the system described in Justis *et al.* uses guidewires (Justis, column 12, lines 44-49) instead of marking pins. In addition, Applicants submit that Justis *et al.* does not disclose a “means for retracting tissue outwardly and

away from said marking pin so as to provide a surgical field of view for insertion of a securing member of a fixation device,” as recited in claim 12.

Based on the foregoing, Applicants respectfully submit that the Examiner’s rejection of claim 12 has been traversed and that claim 12 is in condition for allowance. Because claim 13 and 14 are dependent on claim 12, Applicants respectfully submit that both claims 13 and 14 are also now in condition for allowance.

The Rejection Under 35 U.S.C. § 103

Claims 1-3 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Kambin (U.S. Patent No. 4,573,448) in view of Mangiardi *et al.* (U.S. Patent No. 5,665,092). Applicants respectfully traverse this rejection.

Under MPEP 2142, the Examiner bears the initial burden of actually supporting any *prima facie* conclusion of obviousness. In order to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art reference (or references) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicants’s disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). Moreover, when the motivation to combine the teachings of the references is not immediately apparent, it is the duty of the Examiner to explain why the combination of the teachings is proper. *Ex parte Skinner*, 2 USPQ2d 1788 (Bd. Pat. App. & Inter. 1986).

The Examiner alleges that Kambin discloses a marking and guidance system comprising a guide tube (12), a penetrating device (16) and a marking pin (18). Contrary to the Examiner’s assertion, however, Kambin is distinguishable from the current invention, because it teaches the use

of a guidewire, not a marking pin. (See Kambin, col. 3, lines 16-19, Fig. 3). As discussed above, the current invention is an improvement over the guidewire system, which provides several technical advantages during surgery. (See, e.g., p. 7, lines 10-26; p. 8 lines 1-15).

The Examiner also alleges that although Kambin does not teach a pushing device to be inserted through the cylindrical channel of the guide tube and provide a driving force to the marking pin, Mangiardi *et al.* discloses such a pushing device (2,4). Even assuming *arguendo* that Mangiardi *et al.* discloses a pushing device, Applicants submit that there is no motivation or suggestion to combine the reference with Kambin. Mangiardi *et al.* discloses a method of using pins as markers for surgery, while Kambin discloses a method of using guidewires for decompressing herniated discs. Due to the differences in purpose and techniques (e.g., guidewires v. marking pins), a person of ordinary skill in the art would not have been motivated to combine these references, nor has the Examiner provided any evidence of such motivation to combine. In fact, Applicants respectfully submit that the pushing device disclosed by Mangiardi would not have worked with the guidewire system of Kambin and, therefore, there would have been no expectation of success or motivation to combine these references by those of ordinary skill in the art. Applicants accordingly submit that the Examiner has improperly combined Kambin with Mangiardi *et al.* and respectfully request the Examiner to withdraw the rejection of claims 1-3, and pass these claims to allowance.

Claim 4 was rejected under U.S.C. 103(a) as allegedly being unpatentable over Kambin (U.S. Patent No. 4,573,448) in view of Mangiardi *et al.* (U.S. Patent No. 5,665,092) in view of Justis *et al.* (U.S. Patent No. 6,530,929). Applicants respectfully traverse this rejection.

As discussed above, Applicants respectfully submit that one of ordinary skill in the art would not have been motivated to combine Mangiardi *et al.* with Kambin. For the same reasons discussed above, Applicants submit that there is no suggestion or motivation to combine Mangiardi *et al.* with Justis *et al.* or Kambin. Accordingly, Applicants respectfully submit that the Examiner's rejection of claim 4 has been traversed and that claim 4 is now in condition for allowance.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicants petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 559552000200. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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